AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES 1 | 42

2. CONTRACT *(Proc. Inst. Ident.)* NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQUEST/PROJECT NO.
75A50119C00043	See Block 20C	OS243651

5. ISSUED BY CODE ASPR-BARDA	6. ADMINISTERED BY *(If other than Item 5)* CODE ASPR-BARDA
ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201	ASPR-BARDA 200 Independence Ave., S.W. Room 638-G Washington DC 20201 SCD-C

7. NAME AND ADDRESS OF CONTRACTOR *(No., street, country, State and ZIP Code)*	8. DELIVERY ☐ FOB ORIGIN ☒ OTHER *(See below)* 9. DISCOUNT FOR PROMPT PAYMENT 10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN / ITEM
SONICA LLC 1544252 Attn: SHUAI XU SONICA LLC 2145 SHERIDAN RD J215 EVANSTON IL 602080834	
CODE 1544252 FACILITY CODE	

11. SHIP TO/MARK FOR CODE HHS/OS/ASPR	12. PAYMENT WILL BE MADE BY CODE PSC
HHS/OS/ASPR 200 C St SW WASHINGTON DC 20201	PSC Program Support Center 7700 Wisconsin Ave Bethesda MD 20814

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:	14. ACCOUNTING AND APPROPRIATION DATA
☐ 10 U.S.C. 2304 (c) ( ) ☐ 41 U.S.C. 3304 (a) ( )	2019.1992019.25106

15A. ITEM NO	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Continued				
	15G. TOTAL AMOUNT OF CONTRACT				$656,420.00

16. TABLE OF CONTENTS

(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
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CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17. ☒ CONTRACTOR' S NEGOTIATED AGREEMENT (*Contractor is required to sign this document and return* 1 *copies to issuing office.)* Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. *(Attachments are listed herein.)*

18. ☐ SEALED-BID AWARD (*Contractor is not required to sign this document.)* Your bid on Solicitation Number _____, including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)

19A. NAME AND TITLE OF SIGNER *(Type or print)*	20A. NAME OF CONTRACTING OFFICER
Shuai Xu - CEO	TROY G. FRANCIS

19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
BY _____ *(Signature of person authorized to sign)*	7/30/2019	BY Troy G. Francis -S Digitally signed by Troy G. Francis -S DN: c=US, o=U.S. Government, ou=HHS, ou=OS, ou=People, 0.9.2342.19200300.100.1.1=2001931480, cn=Troy G. Francis -S Date: 2019.08.01 19:09:07 -04'00' *(Signature of the Contracting Officer)*	8/1/2019

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Previous edition is NOT usable

STANDARD FORM 26 (Rev. 3/2013)
Prescribed by GSA - FAR (48 CFR) 53.214(a)

NAME OF OFFEROR OR CONTRACTOR

SONICA LLC 1544252

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Tax ID Number: 82-4003472 DUNS Number: 081039857 ASPR-19-03480 - Base Period funding for Sonica Delivery: 08/01/2019 Appr. Yr.: 2019 CAN: 1992019 Object Class: 25106 Period of Performance: 08/01/2019 to 03/31/2021				
1	ASPR-19-03480 - Base Period funding for Sonica Obligated Amount: $656,420.00				656,420.00

DRIVE EZ-BAA STANDARD CONTRACT (V.2.1)

PART I. THE SCHEDULE

SECTION A. ABSTRACT

In 2018, the Biomedical Advanced Research and Development Authority (BARDA) established the Division of Research, Innovation, and Venture (DRIVe). The mission of DRIVe is to encourage agile business practices, accelerate biomedical innovations, and improve the availability of transformative products & technologies to proactively protect Americans from natural and intentional health security threats. The following contract and the Statement of Work (addressed in Section C), further the mission and goals of DRIVe.

SECTION B. SUPPLIES OR SERVICES AND PRICES/COSTS

B. I. PRICE

a. FIRM FIXED PRICE: The firm fixed price of the base period of the contract is $656,420.

.

ITEM NO.	DESCRIPTION OF ITEM	PERIOD OF PERFORMANCE	QUANTITY	UNIT	UNIT PRICE
0001	Advanced, Bio-Integrated, and Cloud-Enabled Sensors for Early Diagnosis of Respiratory Infections in the Home Setting	01 August 2019 - 31 March 2021	1	EA	$656,420

B. II.

Through negotiations, the Government and Contractor agreed that a total price of $979,030 would be a realistic and reasonable estimate of Contractor's actual costs of performance. Accordingly, in return for successful completion and delivery of CLIN 0001, the Government's portion will be $656,420.

B. III. ADVANCE UNDERSTANDINGS

a. Sharing of contract deliverables within United States Government (USG)

In an effort to build a robust medical countermeasure pipeline through increased collaboration, the Government may share technical deliverables with Government entities responsible for Medical Countermeasure Development. In accordance with recommendations from the Public Health Emergency Medical Countermeasure Enterprise Review, agreements established in the Integrated Portfolio Advisory Committee (PAC) Charter, and agreements between BARDA and the Department of Defense, the National Institutes of Health, the Centers for Disease Control, and the Food and Drug Administration, BARDA may share technical deliverables and test results created in the performance of this Contract with colleagues within the Integrated Portfolio. This advance understanding does not authorize the Government to share financial information outside of the United States Government. The Contractor is advised to review the terms of FAR 52.227-14, Rights in Data – General, regarding the government's rights to deliverables submitted during performance as well as the government's rights to data contained within those deliverables.

b. Approval of Human and Animal Protocols

This contract:

1. [X] **Will** or ☐ **Will Not** include clinical trials (e.g. human protocols); and
2. ☐ **Will** or [X] **Will Not** include non-clinical trials (e.g. animal protocols).

Accordingly, if checked to indicate either class of studies is *not* included under the subject contract, all of the corresponding clauses/obligations included in this document are hereby self-deleting.

The Contractor shall submit all human and animal protocols and human informed consent documents as referenced under this Contract to the COR for review and approval **prior** to seeking other approvals (Institutional Review Board, Human Use Committee, Institutional Animal Care and Use Committee). The Government requires no fewer than eight (8) business days to perform a review. The Contractor shall take this review time into account and submit protocols as early as possible to avoid delays. The Government's comments and feedback shall be addressed prior to approval. The COR will review and provide approval of protocols. Human informed consents shall also be submitted and reviewed with any human protocol.

c. Rights in Data

See Section I – Contract Clauses

SECTION C. DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

C. I. STATEMENT OF WORK

See Section J, Attachment 1 (Statement of Work) as agreed upon by the Government and Contractor, and the Reporting Requirements outlined by "DRIVe Digital Resources" accessed via www.drive.hhs.gov .

C. II. REGULATORY ACTIVITIES

The Contractor shall submit to the COR for review and acceptance, pre-submission documents, submission documents, results documents, and all proposed regulatory filing documents with the FDA.

C. III. QUALITY

The Contractor may be required to establish and maintain a Quality Management System for the proposed effort with sufficient content to include but not limited to the elements contained in the Code of Federal Regulations Title 21 Part 820.

The Contractor may be required to establish routine internal reviews of the proposed effort with documentation and evidence of the ability to maintain, and adhere to the Code of Federal Regulations Title 21 Part 820.

The Contractor may be required to subcontract for an independent audit of its system quality system adherence, resolve any issues noted by the auditor, and provide the audit findings and resolutions to the Government.

SECTION D. PACKAGING, MARKING, AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications and Section F. At a minimum, all deliverables shall be marked with the contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition

Unless otherwise specified by the CO, delivery of reports to be furnished to the Government under this contract (including invoices) shall be delivered to the CO and COR electronically along with a concurrent email notification to the CO and COR (as defined in Section F.3. Electronic Submission) summarizing the electronic delivery.

SECTION E. INSPECTION AND ACCEPTANCE

E.I. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

See Section I for a complete list of clauses incorporated by reference.

E.II. DESIGNATION OF GOVERNMENT PERSONNEL

For the purpose of this Section E, the designated Contracting Officer's Representative (COR) is the authorized representative of the Contracting Officer. The COR will assist in resolving technical issues that arise during performance. The COR however is not authorized to change any contract terms or authorize any changes in the Statement of Work or modify or extend the period of performance, or authorize reimbursement of any costs incurred during performance.

E.III. INSPECTION, ACCEPTANCE AND CONTRACT MONITORING

Inspection and acceptance of the product, services, and documentation called for herein shall be accomplished by the Contracting Officer or a duly authorized representative. Delivery, technical inspection and acceptance will be take place at a location designated by the Contracting Officer or at:

Office of the Assistant Secretary for Preparedness and Response
Biomedical Advanced Research and Development Authority
O'Neill House Office Building
Washington, DC 20515

At the discretion of the Government and independent of activities conducted by the Contractor, with 48 hours' notice to the Contractor, the Government reserves the right to conduct site visits and inspections related to this Contract on an as needed basis during normal business hours, including collection of product samples and intermediates held at the location of the Contractor, or its subcontractor. All costs reasonably incurred by the Contractor and subcontractor for such visit and/or inspection shall be allowable costs subject to the Allowable cost requirements in FAR Subpart 31.2. The Contractor shall coordinate these visits and shall have the opportunity to accompany the Government on any such visits. Under time-sensitive or critical situations, the Government reserves the right to suspend the 48 hour notice to the Contractor. The areas included under the site visit could include, but are not limited to: security, regulatory and quality systems, manufacturing processes and cGMP/GLP/GCP compliance related to activities funded under this Contract.

If the Government, Contractor, or other party identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the Government for review and acceptance

- If issues are identified during the audit, the Contractor shall submit a report to the CO and COR within five (5) business days detailing the finding and corrective action(s) of the audit.
- COR and CO will review the report and provide a response to the Contractor within ten (10) business days.
- Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

SECTION F. DELIVERIES OR PERFORMANCE

F.I. ESTIMATED PERIOD OF PERFORMANCE

The estimated period of performance for this contract shall be **20 months** from the award date.

F.II. DELIVERABLES

Successful performance of the final contract shall be deemed to occur upon completion of performance of the work set forth in Attachment 1 of this contract and upon delivery and acceptance, as required by the Attachment 1, by the COR, and of each of the deliverables described in Section C and Section F below.

All deliverables and reporting documents listed within this Section shall be delivered electronically to the CO, CS, and the COR unless otherwise specified by the CO.

Number	Deliverable	Description	Due
1	Kickoff Meeting	The Contractor shall complete a Kickoff meeting after contract award. Both as a videoconference and an in-person meeting. Contractor shall provide itinerary and agenda at least 2 business days in advance of meeting.	Within 30 calendar days of award date for video conference and 90 days for an in-person meeting
2	Monthly Teleconference and Ad-Hoc Meetings (as needed)	The Contractor shall participate in teleconferences every month with BARDA to discuss the performance of the contract. Interim ad-hoc meetings may also be scheduled as needed. The Contractor shall provide slides 24 hours in advance of scheduled meeting.	Held monthly. Additional ad-hoc meetings to be held as needed. Minutes provided by contractor within 7 business days of the meeting.
3	Monthly Reports	Submit monthly reports summarizing data and progress to date on each aim in the SOW.	Due the 15th of the month following the preceding reporting month. The COR and CO will review the monthly reports with the Contractor and provide feedback
4	Product/Technology Transition Strategy	Contractor shall provide a 1-2 page summary document containing a Transition Strategy. The Transition Strategy should provide a strategic business and technical plan for further	Contractor shall provide the Transition Strategies 30 days prior to the end of each year of the Base Period.

		development and transitioning the product and/or technology	
5	Sample Prototype	If applicable and available, the Contractor shall deliver sample prototype/examples to DRIVe for display purposely ONLY. Prototype/examples are not intended for clinical or non-clinical uses.	Prototype shall be delivered 30 days from request if available
6	Final Data Submission Package	Contractor must submit a data package consisting of all raw data produced under this contract. Data may be used by DRIVe for analysis, evaluation, shared with other agencies, or shared outside of the government consistent with FAR 52.227-14. This submission package must be delivered in a non-proprietary format. If clinical trial data is included, that data must be provided consistent with applicable privacy laws to protect personally identifiable information (PII).	Contractor will submit at least 15 days prior to contract end date. Partial data-sets may also be requested for delivery prior to submission of the Final Data Submission Package.
7	Draft Final Report & Final Report	These reports are to include a summation of the work performed and results obtained for the entire contract period of performance.	Draft Final Report to the COR and CO 30 calendar days prior to contract end date, Final Report shall be delivered on or before the completion date of the contract.
8	Supplemental Technical Documents, Raw Data, or Data Analysis	Upon request and also as part of deliverables the Contractor shall provide raw data, data analysis, or data report to BARDA.	Contractor shall provide the Technical Documents upon request from the CO or COR

a. Detailed Descriptions of Select Contract Deliverables

i. Technical Progress Reports

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with this Article F of this contract.

ii. Monthly Progress Report

The contents of the monthly report will be agreed upon between Contractor and COR, such that a minimum administrative burden is necessary to document technical progress.

iii. Draft Final Report and Final Report

These reports are to include a summation of the work performed and results obtained for the entire contract

period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Draft Final Report and Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of the contract. The Draft Final Report and the Final Report shall be submitted in accordance with the dates set forth in the tables above. The report should conform to the following format:

1. Cover page to include the contract number, contract title, performance period covered, Contractor's name and address, telephone number, fax number, email address and submission date.

2. SECTION I: EXECUTIVE SUMMARY - Summarize the purpose and scope of the contract effort including a summary of the major accomplishments relative to the specific activities set forth in the Statement of Work.

3. SECTION II: RESULTS - A detailed description of the work performed related the Gantt chart, the results obtained, and the impact of the results on the scientific and/or public health community including a listing of all manuscripts (published and in preparation) and abstracts presented during the entire period of performance and a summary of all inventions.

Draft Final Report: The Contractor is required to submit the Draft Final Report to the COR and CO. The COR and CO will review the Draft Final Report and provide the Contractor with comments.

Final Report: The final version shall include or address the COR's and CO's written comments on the draft report. Final Report shall be submitted on or before the completion date of the contract.

a. Summary of Salient Results: Within the Final Report, the Contractor shall submit Final Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

Periodic Document Review: The CO and COR reserve the right to request a non-proprietary technical document for distribution within the Government. Contractor shall provide technical document within 10 business days of CO or COR request. Contractor can request additional time on an as needed basis. If edits are recommended, the Contractor must address, in writing, concerns raised by BARDA in writing.

F.III. SUBJECT INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor, including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. A final invention statement (see FAR 27.303 (b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

SECTION G. CONTRACT ADMINISTRATION DATA

G.I. CONTRACTING OFFICER

The following Contracting Officer (CO) will represent the Government for the purpose of this contract:

Troy Francis
Contracting Officer
HHS/ASPR/AMCG
O'Neill House Office Building
Washington, DC 20515
troy.francis@hhs.gov

1) The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions, or other stipulations of this contract.
2) The Contracting Officer is the only person with the authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimburse to the Contractor of any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract.
3) No information other than that which may be contained in an authorized modification to this contract, duly issued by the Contracting Officer, which may be received from any person employed by the US Government, other otherwise, shall be considered grounds for deviation from any stipulation of this contract.
4) The Government may unilaterally change its CO designation, after which it will notify the Contractor in writing of such change.

G.II. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following Contracting Officer's Representative (COR) and Alternate Contracting Officer's Representative (ACOR) will represent the Government for the purpose of this contract:

Justin Yang
Contracting Officer's Representative
HHS/ASPR/BARDA
O'Neill House Office Building
Washington, DC 20515
ge.yang@hhs.gov

Rachel Evans
Alternate Contracting Officer's Representative
HHS/ASPR/BARDA
O'Neill House Office Building
Washington, DC 20515
rachel.evans@hhs.gov

The COR and ACOR are responsible for:

1) Monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements;
2) Assisting the Contracting Officer in interpreting the statement of work and any other technical performance requirements;
3) Performing technical evaluation as required;
4) Performing technical inspections and acceptances required by this contract; and
5) Assisting in the resolution of technical problems encountered during performance. The Government may unilaterally change its COR or ACOR designation, after which it will notify Contractor in writing of such change.

G.III. KEY PERSONNEL

Per HHSAR 352.237-75 incorporated in Section I of this contract, the following individuals are considered to be essential to the work being performed hereunder:

Name	Title
Steve Xu	CEO
John Rogers	CBIE Executive Director
John Lee	Electrical Engineer/Regulatory Consultant
Julie Lee	Software Engineer
Dennis Ryu	Hardware Engineer
Edward Kim	Data Scientist/Cloud Engineer
Kelly Cao	Industrial Engineer/Designer
Anthony Banks	Engineer/Project Manager

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) and qualifications of the individual proposed as a substitute to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

G.IV. INVOICING

a) Invoices will be submitted for each deliverable in accordance with Attachment 3. The line entries for subdivisions of work and elements of cost (expenditure categories), which shall be reported within the total contract, are discussed in Section J. In the event that a deliverable is not submitted or not deemed acceptable for approval by the COR and CO, the CO reserve the right to not process the invoice and payment until an acceptable deliverable has been submitted and approved by the COR and CO.

b) Invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government.

c) The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number. Contractor invoices shall conform to the form, format, and content requirements of the instructions for Invoice/Financing requests and Contract Financial Reporting, and be sent to the following points of contact:

PSC
PSC_Invoices@psc.hhs.gov &"DRIVe Digital Resources"

d) An electronic copy of the payment request shall be uploaded into the designated digital repository (DRIVe digital resource) and an e-mail notification of the upload will be provided to the CO and COR.

** All invoice submissions shall be in accordance with FAR Clause 52.232-25, Prompt Payment (Oct 2008)

G.V. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

i) Contractor Performance Evaluations

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, an interim evaluation shall be submitted annually.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

ii) Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:

http://www.cpars.csd.disa.mil/cparsmain.htm

The registration process requires the Contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the Contractor will be required to identify an alternate contact that will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

G.VI. CONTRACT COMMUNICATIONS/CORRESPONDENCE (JULY 1999)

The Contractor shall identify all correspondence, reports, and other data pertinent to this contract by imprinting the contract number from Page 1 of the contract.

G.VII. GOVERNMENT PROPERTY

In addition to the requirements of the Government Property clause incorporated in Section I of this contract, if applicable, the Contractor shall comply with the provisions of HHS Publication, "HHS Contracting Guide for Control of Government Property," which is incorporated into this contract by reference. This document can be accessed at:

http://www.hhs.gov/hhsmanuals/ (HHS Logistics Management Manual)

Among other issues, this publication provides a summary of the Contractor's responsibilities regarding purchasing authorizations and inventory and reporting requirements under the contract.

Notwithstanding the provisions outlined in the HHS Publication, "HHS Contracting Guide for Control of Government Property," which is incorporated in this contract in paragraph 1. above, the Contractor shall use the form entitled, "Report of Government Owned, Contractor Held Property" for submitting summary reports required under this contract, as directed by the Contracting Officer or his/her designee.

Note: Contractor retains title to all property acquired by the contractor for use under this contract.

SECTION H. SPECIAL CONTRACT REQUIREMENTS

If the proposed effort involves animal use or human subject research (as identified above in Section B), additional provisions will be provided during negotiations or via the "DRIVe Digital Resources" accessed via www.drive.hhs.gov .

H.I. Engagement with The U.S. Food and Drug Administration (FDA)

1) FDA Meetings

i. The Contractor shall forward the dates and times of any meeting with the FDA to BARDA and make arrangements for appropriate BARDA staff to attend the FDA meetings. BARDA staff shall include up to a maximum of four people (COR, CO and up to 2 subject matter experts).

ii. Contractor shall notify BARDA of upcoming FDA meetings within 24 hours of scheduling.

iii. The Contractor shall forward initial Contractor and FDA-issued draft minutes and final minutes of any meeting with the FDA to the CO and COR within 5 business days of receipt. All documents shall be duly marked as either "Draft" or "Final."

2) FDA Submissions

i. The Contractor shall provide the COR all documents submitted to the FDA, including an electronic copy of the final FDA submission. All documents shall be duly marked as either "Draft" or "Final."

1. If draft documents are submitted to the COR for review, the COR will provide feedback to Contractor within 10 business days of receipt.

2. If BARDA reviews draft documents, the Contractor shall revise their documents to address BARDA's written concerns and/or recommendations prior to FDA submission.

3. Final FDA submissions shall be submitted to the CO and COR concurrently or no later than 5 calendar days of their submission to FDA.

3) FDA Audits

i. In the event of an FDA inspection which occurs as a result of this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the CO and COR with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR) within five (5) business days after the Contractors receipt of those documents. The Contractor shall provide the COR and CO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector.

ii. If draft documents are submitted to the COR for review, the COR will provide feedback to Contractor within 10 business days of receipt.

iii. If BARDA reviews draft documents, the Contractor shall revise their documents to address BARDA's written concerns and/or recommendations prior to FDA submission.

1. Contractor shall notify CO and COR within 10 business days of a scheduled FDA audit or within 24 hours of an ad hoc site visit/audit if the FDA does not provide advanced notice.

2. Contractor shall provide copies of any FDA audit report received from subcontractors that occur as a result of this contract or for this product within 5 business days of receiving correspondence from the FDA, Subcontractor, or third party.

3. Within 15 business days of audit report, Contractor shall provide CO with a plan for addressing areas of nonconformance, if any are identified.

Final FDA submissions shall be submitted to the CO and COR.

4) Other FDA Correspondence

The Contractor shall memorialize any correspondence between Contractor and FDA as related to activities funded under this contract and submit to BARDA. All documents shall be duly marked as either "Draft" or "Final." Contractor shall provide written summary of any FDA correspondence within 5 business days of correspondence.

H.II. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in BARDA funded programs should report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is 1-800-HHS-TIPS (1-800- 447-8477). All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE, P.O. Box 23489
Washington, D.C. 20026

H.III. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

H.IV. IDENTIFICATION AND DISPOSITION OF DATA

The Contractor will be required to provide certain data generated under this contract to the Department of Health and Human Services (DHHS). DHHS reserves the right to review any other data determined by DHHS to be relevant to this contract. The Contractor shall keep copies of all data required by the Food and Drug Administration (FDA) relevant to this contract for the time specified by the FDA.

H.V. EXPORT CONTROL NOTIFICATION

Contractors are responsible for ensuring compliance with all export control laws and regulations that may be applicable to the export of and foreign access to their proposed technologies. Contractors may consult with the Department of State with any questions regarding the International Traffic in Arms Regulation (ITAR) (22 CRF Parts 120-130) and /or the Department of Commerce regarding the Export

Administration Regulations (15 CRF Parts 730-774).

H.VI. CONFLICT OF INTEREST

The Contractor represents and warrants that, to the best of the Contractor's knowledge and belief, there are no relevant facts or circumstances which could give rise to an organizational conflict of interest, as defined in FAR 2.101 and Subpart 9.5, or that the Contractor has disclosed all such relevant information. Prior to commencement of any work, the Contractor agrees to notify the Contracting Officer promptly that, to the best of its knowledge and belief, no actual or potential conflict of interest exists or to identify to the Contracting Officer any actual or potential conflict of interest the firm may have. In emergency situations, however, work may begin but notification shall be made within five (5) working days. The Contractor agrees that if an actual or potential organizational conflict of interest is identified during performance, the Contractor shall promptly make a full disclosure in writing to the Contracting Officer. This disclosure shall include a description of actions which the Contractor has taken or proposes to take, after consultation with the Contracting Officer, to avoid, mitigate, or neutralize the actual or potential conflict of interest. The Contractor shall continue performance until notified by the Contracting Officer of any contrary action to be taken. Remedies include termination of this contract for convenience, in whole or in part, if the Contracting Officer deems such termination necessary to avoid an organizational conflict of interest. If the Contractor was aware of a potential organizational conflict of interest prior to award or discovered an actual or potential conflict after award and did not disclose it or misrepresented relevant information to the Contracting Officer, the Government may terminate the contract for default, debar the Contractor from Government contracting, or pursue such other remedies as may be permitted by law or this contract.

H.VII. INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST

The Contractor shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under BARDA contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest.

If the failure of an Investigator to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the BARDA-funded research, the Contractor must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will consider the situation and, as necessary, take appropriate action or refer the matter to the Contractor for further action, which may include directions to the Contractor on how to maintain appropriate objectivity in the BARDA-funded research project.

The Contracting Officer and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests, and the Contractor’s review of, and response to, such disclosure, regardless of whether the disclosure resulted in the Contractor’s determination of a financial conflict of interests. The Contracting Officer may require submission of the records or review them on site. On the basis of this review of records or other information that may be available, the Contracting Officer may decide that a particular financial conflict of interest will bias the objectivity of the BARDA-funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with 45 CFR Part 94. The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that BARDA-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not disclosed managed or reported the Contractor shall require the Investigator involved to disclose the financial

conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

H.VIII. NEEDLE DISTRIBUTION

The Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

H.IX. RESTRICTION ON ABORTIONS

The Contractor shall not use contract funds for any abortion.

H.X. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

H.XI. CONFIDENTIALITY OF INFORMATION

a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the USG will furnish to the Contractor or that the Contractor is expected to generate which is confidential and providing further that the Government is not entitled to unlimited rights to that information pursuant to FAR 52.227-14. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

H.XII. ACCESS TO DOCUMENTATION/DATA

The Government shall have physical and electronic access to all documentation and data generated under this contract, including: all data documenting Contractor performance; all data generated; all communications and correspondence with regulatory agencies and bodies to include all audit observations, inspection reports, milestone completion documents, and all Offeror commitments and responses. Contractor shall provide the Government with an electronic copy of all correspondence and submissions to the FDA within 5 business days of receipt. The Government shall acquire unlimited rights to all data funded under this contract in accordance with FAR Subpart 27.4 and FAR Clause 52.227-14.

H.XIII. ACKNOWLEDGMENT OF FEDERAL FUNDING

Section 507 of P.L. 104-208 mandates that Contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. This requirement is in addition to the continuing requirement to provide an acknowledgment of support and disclaimer on any publication reporting the results of a contract funded activity.

a. Publication and Publicity

No information related to data obtained under this contract shall be released or publicized without providing BARDA with at least thirty (30) days advanced notice and an opportunity to review the proposed release or publication.

In addition to the requirements set forth in HHSAR Clause 352.227-70, Publications and Publicity incorporated by reference in Section I of this contract, Section 507 of P.L. 104-208 mandates that Contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. Contractors are required to state:

1) The percentage and dollar amounts of the total program or project costs financed with Federal money and;

2) The percentage and dollar amount of the total costs financed by non-governmental sources. For purposes of this contract "publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of information, including any manuscript or scientific meeting abstract. Any publication containing data generated under this contract must be submitted for BARDA review no less than thirty (30) calendar days for manuscripts and fifteen (15) calendar days for abstracts before submission for public presentation or publication. Contract support shall be acknowledged in all such publications substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, DRIVe, under the this contract."

b. Press Releases

Misrepresenting contract results or releasing information that is injurious to the integrity of BARDA may be construed as improper conduct. Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. With the exception of ad-hoc press releases required by applicable law or regulations, the Contractor shall ensure that the COR has received an advance copy of any press release related to the contract not less than two (2) business days prior to the issuance of the press release.

The Contractor shall acknowledge the support of the Department of Health and Human Service, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, DRIVe, under this contract."

c. Contractor Use of the Powered by DRIVe Logo

1) For the limited purposes of the Contractor's participation related to the subject DRIVe contract,

Contractor is permitted to use the following logo (the "Logo") for the period of the Term (or for a longer period, if agreed between the Parties), subject to the Contractor's full performance of the terms and conditions of the subject contract and provided that Contractor shall cease to use the Logo immediately upon BARDA's request.

2) The Contractor's use of the term "Powered by DRIVe" shall be subject to DRIVe Brand Guidelines.

3) Any other use of the DRIVe name, its Logo, servicemarks or trademarks, or any of its other distinguishable marks, whether registered or not, shall be limited to those granted by the express, written permission of the BARDA. Those to whom such permission is granted must agree that BARDA shall remain the final arbiter of the use of the mark or Logo.

d. BARDA Use of Contractor Logo

Contractor hereby grants BARDA/DRIVe the right to use Contractor's corporate logo (and other artwork as agreed to by the Parties), for presentations, internal and external websites, and other reasonable promotional and reporting uses relating to the Project during the Term (or for a longer period, if agreed between the Parties).

H.XIV. PRIVACY ACT APPLICABILITY

Notification is hereby given that the Contractor and its employees are subject to criminal penalties for violation of the Privacy Act to the same extent as employees of the Government. The Contractor shall assure that each of its employees knows the prescribed rules of conduct and that each is aware that he or she can be subjected to criminal penalty for violation of the Act. A copy of 45 CFR Part 5b, Privacy Act Regulations, may be obtained at https://www.gpo.gov/fdsys/granule/CFR-2007- title45-vol1/CFR-2007-title45-vol1-part5b

The Project Officer is hereby designated as the official who is responsible for monitoring contractor compliance with the Privacy Act.

The Contractor shall follow the Privacy Act guidance as contained in the Privacy Act System of Records number 09-25-0200.

H.XV. LABORATORY LICENSE REQUIREMENTS

The Contractor shall comply with all applicable requirements of Section 353 of the Public Health Service Act (Clinical Laboratory Improvement Act as amended) (42 U.S.C. 263a and 42 CFR Part 493). This requirement shall also be included in any subcontract for services under the contract.

H.XVII. QUALITY ASSURANCE (QA) AUDIT REPORTS

BARDA reserves the right to participate in QA audits as related to activities funded under this contract. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor,

detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution.

- Contractor shall notify CO and COR of upcoming, ongoing, or recent audits/site visits of subcontractors as part of weekly communications.
- Contractor shall notify the COR and CO within five (5) business days of report completion.

H.XVIII. BARDA AUDITS

Contractor shall accommodate periodic or reasonable ad hoc site visits during normal business hours by the Government with forty-eight (48) hours advance notice. If the Government, the Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the Government.

- If issues are identified during the audit, Contractor shall submit a report to the CO and COR detailing the finding and corrective action(s) within 10 business days of the audit.
- COR and CO will review the report and provide a response to the Contractor with ten (10) business days.
- Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

H.XIX. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS

The Contractor shall not use contract funds to employ workers described in Section 274A (h)(3) of the Immigration and National Act, which reads as follows:

"(3) Definition of unauthorized alien – As used in this Section, the term 'unauthorized alien' with respect to the employment of an alien at a particular time, that the alien is not at that time either an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or by the Attorney General."

H.XX. NOTIFICATION OF CRITICAL PROGRAMMATIC CONCERNS, RISKS, OR POTENTIAL RISKS

If any action occurs that creates a cause for critical programmatic concern, risk, or potential risk to BARDA or the Contractor and Incident Report shall be delivered to BARDA.

- Within 48 hours of activity or incident or within 24 hours for a security related activity or incident, Contractor must notify BARDA.
- Additional updates due to COR and CO within 48 hours of additional developments.
- Contractor shall submit within 5 business days a Corrective Action Plan (if deemed necessary by either party) to address any potential issues.

If corrective action is deemed necessary, Contractor must address in writing, its consideration of concerns raised by BARDA within 5 business days.

H.XXI. DISSEMINATION OF INFORMATION (May 2004)

Other than scientific and technical Sections for which the contractor can assert a copyright under FAR Clause 52.227-14 (c) no information related to data obtained under this contract shall be released or publicized without the prior written consent of the Contracting Officer. In the event that the contractor seeks to publicize data through a scientific or technical Section, the contractor shall provide BARDA, through the COR, with a minimum of thirty (30) business days to review the Section prior to publication.

H.XXII. REGISTRATION WITH THE SELECT AGENT PROGRAM FOR WORK INVOLVING THE POSSESSION, USE, AND/OR TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

Work involving select biological agents or toxins shall not be conducted under this contract until the Contractor and any affected subcontractor(s) are granted a certificate of registration or are authorized to work with the applicable select agents.

For prime or subcontract awards to domestic institutions who possess, use, and/or transfer Select Agents under this contract, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before performing work involving Select Agents, in accordance with 42 CFR 73. No Government funds can be used for work involving Select Agents, as defined in 42 CFR 73, if the final registration certificate is denied.

For prime or subcontract awards to foreign institutions who possess, use, and/or transfer Select Agents under this contract, the institution must provide information satisfactory to the Government that a process equivalent to that described in 42 CFR 73 (http://www.cdc.gov/od/sap/docs/42cfr73.pdf) for U.S. institutions is in place and will be administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. The Contractor must provide information addressing the following key elements appropriate for the foreign institution: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regulations and policies equivalent to 42 CFR 73. The Government will assess the policies and procedures for comparability to the U.S. requirements described in 42 CFR Part 73. When requested by the contracting officer, the Contractor shall provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes summaries of safety, security, and training plans, and applicable laws, regulations, and policies. For the purpose of security risk assessments, the Contractor must provide the names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals have access to Select Agents under the contract.

Listings of HHS select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at https://www.selectagents.gov/

H.XXIII. MANUFACTURING STANDARDS

The Good Manufacturing Practice Regulations (GMP)(21 CFR Parts 820) will be the standard to be applied for manufacturing, processing, packaging, storage and delivery of this product.

If at any time during the life of the contract, the Contractor fails to comply with GMP in the manufacturing, processing, packaging, storage, stability and other testing of the manufactured drug substance or product and delivery of this product and such failure results in a material adverse effect on the safety, purity or potency of the product (a material failure) as identified by the FDA, the Contractor shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. If, within the thirty (30) calendar day period, the Contractor fails to take such an action to the satisfaction of the Government Project Officer, or fails to provide a remediation plan that is acceptable to the COR, then the contract may be terminated.

H.XXIV. SHARING RESEARCH DATA

The Contractor's data sharing plan, due date to be determined at contract award, is hereby incorporated by reference. The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

BARDA endorses the sharing of final research data to serve health. This contract is expected to generate research data that must be shared with the public and other researchers.

BARDA recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS-published documentation on the Health Information Privacy at http://www.hhs.gov/ocr/privacy/index.html). The rights and privacy of people who participate in BARDA-funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

H.XXV. CONTINUED BAN ON FUNDING ABORTION AND CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH, HHSAR 352.270-13 (December 2015)

a) The Contractor shall not use any funds obligated under this contract for any abortion.

b) The Contractor shall not use any funds obligated under this contract for the following:

i. The creation of a human embryo or embryos for research purposes; or

ii. Research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury of death greater than that allowed for research on fetuses in utero under 45 CFR part 46 and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

c) The term ``human embryo or embryos'' includes any organism, not protected as a human subject under 45 CFR part 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes of human diploid cells.

d) The Contractor shall not use any Federal funds for the cloning of human beings.

H.XXVI. PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM ASPR FUNDED RESEARCH

All ASPR-funded investigators shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, of any peer-reviewed scientific publications resulting from research supported in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response. ASPR defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and ASPR. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

H.XXVII. INSTITUTIONAL RESPONSIBILITY REGARDING CONFLICTING INTERESTS OF INVESTIGATORS

The Contractor shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that investigators (defined as the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded under BARDA contracts) will not be biased by any conflicting financial interest.

As required by 45 CFR Part 94, the Contractor shall, at a minimum:

e. Maintain a written, enforceable policy on conflict of interest that complies with 45 CFR Part 94 and inform each investigator of the policy, the investigator's reporting responsibilities, and the applicable regulations. The Contractor must take reasonable steps to ensure that investigators working as collaborators or subcontractors comply with the regulations.

f. Designate an official(s) to solicit and review financial disclosure statements from each investigator participating in BARDA-funded research. Based on established guidelines consistent with the regulations, the designated official(s) must determine whether a conflict of interest exists, and if so, determine what actions should be taken to manage, reduce, or eliminate such conflict. A conflict of interest exists when the designated official(s) reasonably determines that a *Significant Financial Interest* could directly and significantly affect the design, conduct, or reporting of the BARDA-funded research. The Contractor may require the management of other conflicting financial interests in addition to those described in this paragraph, as it deems appropriate. Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests are included in 45 CFR Part 94, under Management of Conflicting Interests.

g. Require all financial disclosures to be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

h. Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the Contractor with respect to each conflicting interest 3 years after final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

i. Establish adequate enforcement mechanisms and provide for sanctions where appropriate.
If a conflict of interest is identified, the Contractor shall report to the Contracting Officer, the existence of the conflicting interest found. This report shall be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis, within sixty (60) days of that identification.

If the failure of an investigator to comply with the conflict of interest policy has biased the design, conduct, or reporting of the BARDA-funded research, the Contractor must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will take appropriate action or refer the matter to the Contractor for further action, which may include directions to the Contractor on how to maintain appropriate objectivity in the funded research.

The Contracting Officer may at any time inquire into the Contractor's procedures and actions regarding conflicts of interests in BARDA-funded research, including a review of all records pertinent to compliance with 45 CFR Part 94. The Contracting Officer may require submission of the records or review them on site. On the basis of this review, the Contracting Officer may decide that a particular conflict of interest will bias the objectivity of the BARDA-funded research to such an extent that further corrective action is needed or that the Contractor has not managed, reduced, or eliminated the conflict of interest. The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that BARDA-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an investigator with a conflict of interest that was not disclosed or managed, the Contractor must require disclosure of the conflict of interest in each public presentation of the results of the research.

H.XXVIII. BARDA SECURITY REQUIREMENTS FOR FACILITIES

Security plan must be provided within 60 days and security remediation plan (if needed) must be required within 120 days. All security requirements must be met prior to commencing manufacturing of any product. See Section C for a detailed list of security requirements.

H.XXIX. CLINICAL TERMS OF AWARD

In addition to those terms and conditions outlined under applicable HHSAR clauses incorporated by reference by Section I of this contract, the following clinical terms of award detail an agreement between the BARDA and the Contractor; they apply to all contracts involving clinical research.

Draft protocols for each clinical study will be submitted to BARDA for evaluation and comment. BARDA comments will be addressed and/or incorporated into the draft protocol prior to submission to the FDA for comment, if required.

BARDA shall have unlimited rights to all protocols, data generated from the execution of these protocols, and final reports, funded by BARDA under this contract, as defined in Rights in Data Clause in FAR 52.227-14. BARDA reserves the right to request that the Contractor provide any contract deliverable in a non-proprietary form without any restrictive legends to ensure BARDA has the ability to review and distribute the deliverables, as BARDA deems necessary.

i. Safety and Monitoring Issues

a. Institutional Review Board or Independent Ethics Committee Approval

Before award and then with the annual progress report, the Contractor must submit to BARDA a copy of the current IRB-or IEC-approved informed consent document, documentation of continuing review and approval and the OHRP federal wide assurance number for the institution or site.

If other institutions are involved in the research (e.g., a multicenter clinical trial or study), each institution's IRB or IEC must review and approve the protocol. They must also provide BARDA initial and annual documentation of continuing review and approval, including the current approved informed consent document and federal wide number.

The Contractor must ensure that the application as well as all protocols are reviewed by their IRB or IEC.

To help ensure the safety of participants enrolled in BARDA-funded studies, the Contractor must provide BARDA copies of documents related to all major changes in the status of ongoing protocols, including the following:

- All amendments or changes to the protocol, identified by protocol version number, date, or both and dates it is valid.
- All changes in informed consent documents, identified by version number, dates, or both and dates it is valid.
- Termination or temporary suspension of patient accrual.
- Termination or temporary suspension of the protocol.
- Any change in IRB approval.
- Any other problems or issues that could affect the participants in the studies.

The Contractor must notify BARDA through the COR or CO of any of the above changes within five (5) working days by email or fax, followed by a letter signed by the institutional business official, detailing notification of the change of status to the local IRB and a copy of any responses from the IRB or IEC.

If a clinical protocol has been reviewed by an institutional biosafety committee (IBC) or the NIH Recombinant DNA Advisory Committee (RAC), the Contractor must provide information about the initial

and ongoing review and approval, if any. See the NIH Guidelines for Research Involving Recombinant DNA Molecules.

b. Data and Safety Monitoring Requirements

BARDA strongly recommends independent safety monitoring for clinical trials of investigational drugs, devices, or biologics; clinical trial of licensed products; and clinical research of any type involving more than minimal risk to volunteers. Independent monitoring can take a variety of forms. Phase III clinical trials must be reviewed by an independent data and safety monitoring board (DSMB); other trials may require DSMB oversight as well. The Contractor shall inform BARDA of any upcoming site visits and/or audits of CRO facilities funded under this effort. BARDA reserves the right to accompany the Contractor on site visits and/or audits of CROs as BARDA deems necessary. The Contractor shall inform BARDA 30 days in advance of a DSMB board meetings for studies funded under this effort. BARDA reserves the right to participate in the DSMB board meetings on an impromptu basis as a non-voting member, if feasible per the structure of the study. If not, the communications from the DSMB to the Contractor should be made available to BARDA upon receipt.

A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For examples, the risk of drawing a small amount of blood from orm a healthy individual for research purposes is no greater than the risk of doing so as part of a routine physical examination (45 CFR 46.102I).

Final decisions regarding the type of monitoring to be used must be made by the Contractor, based on FDA and BARDA guidance, before enrollment starts. Discussions with the responsible BARDA PO regarding appropriate safety monitoring must take place, and the Contractor must submit a written response to all concerns raised by BARDA, before patient enrollment begins and may include discussions about the appointment of one of the following:

Independent Safety Monitor – a physician or other appropriate expert who is independent of the study and available in real time to review and recommend appropriate action regarding adverse events and other safety issues.

Independent Monitoring Committee (IMC) or Safety Monitoring Committee (SMC) – a small group of independent investigators and biostatisticians who review data from a particular study.

Data and Safety Monitoring Board – an independent committee charged with reviewing safety and trial progress and providing advice with respect to study continuation, modification, and termination. The Contractor may use an established BARDA DSMB or to organize an independent DSMB. All phase III clinical trials must be reviewed by a DSMB; other trials may require DSMB oversight as well. Please refer to: NIAID Principles for Use of a Data and Safety Monitoring Board (DSMB) For Oversight of Clinical Trials Policy. BARDA should be provided documentation from DSMB and should be provided with any decisions by Contractor regarding the DMSB as it relates to work under this contract.

When a monitor or monitoring board is organized, a description of it, its charter or operating procedures (including a proposed meeting schedule and plan for review of adverse events), and roster and curriculum vitae from all members must be submitted to BARDA before enrollment starts. If concerns are raised, Contractor must address all concerns to BARDA, in writing, before enrollment begins. The Contractor will also ensure that the monitors and board members report any conflicts of interest and the Contractor will maintain a record of this. The Contractor will share conflict of interest reports with BARDA.

Additionally, the Contractor must submit written summaries of all reviews conducted by the monitoring group to the BARDA within thirty (30) days of reviews or meetings.

ii. BARDA Protocol Review Process Before Patient Enrollment Begins

BARDA has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in BARDA-supported clinical trials. Therefore, before patient accrual or participant enrollment, the Contractor must ensure the following (as applicable) are in place at each participating institution, prior to patient accrual or enrollment:

- IRB- or IEC-approved clinical research protocol identified by version number, date, or both, including details of study design, proposed interventions, patient eligibility, and exclusion criteria.
- Documentation of IRB or IEC approval, including OHRP federal wide number, IRB or IEC registration number, and IRB and IEC name.
- IRB- or IEC- approved informed consent document, identified by version number, date, or both and dates it is valid.
- Plans for the management of side effects.
- Procedures for assessing and reporting adverse events.
- Plans for data and safety monitoring (see above) and monitoring of the clinical study site, pharmacy, and laboratory.
- Documentation that the Contractor and all study staff responsible for the design or conduct of the research have received training in the protection of human subjects.

Documentation to demonstrate that each of the above items are in place shall be submitted to BARDA) for evaluation and comment in conjunction with the protocol. Execution of clinical studies requires written authorization from BARDA in accordance with this section of this contract.

iii. Investigational New Drug or Investigational Device Exemption Requirements

Consistent with federal regulations, clinical research projects involving the use of investigational therapeutics, vaccines, or other medical interventions (including licensed products and devices for a purpose other than that for which they were licensed) in humans under a research protocol must be performed under a Food and Drug Administration (FDA) investigational new drug (IND) or investigational device exemption (IDE).

Exceptions must be granted in writing by FDA. If the proposed clinical trial will be performed under an IND or IDE, the Contractor must provide BARDA with the name and institution of the IND or IDE sponsor, the date the IND or IDE was filed with FDA, the FDA IND or IDE number, any written comments from FDA, and the written responses to those comments.

Unless FDA notifies Contractor otherwise, The Contractor must wait thirty (30) calendar days from FDA receipt of an initial IND or IDE application before initiating a clinical trial.

The Contractor must notify BARDA if the FDA places the study on clinical hold and provide BARDA any written comments from FDA, written responses to the comments, and documentation in writing that the hold has been lifted.

The Contractor must not use grant or contract funds during a clinical hold to fund clinical studies that are on hold other than costs that are associated with activities related to patients coming off study, monitoring, or ending the study.. The Contractor must not enter into any new financial obligations related to clinical activities for the clinical trial on clinical hold.

iv. Required Time-Sensitive Notification

a. Under an IND or IDE, the sponsor must provide FDA safety reports of serious adverse events. Under these Clinical Terms of Award, the Contractor must submit copies to the responsible BARDA representative or the Contracting Officer's Representative (COR) as follows:

- Expedited safety report of unexpected or life-threatening experience or death. A copy of any report of

unexpected or life-threatening experience or death associated with the use of an IND drug, which must be reported to FDA by telephone or fax as soon as possible but no later than seven (7) days after the IND sponsor's receipt of the information, must be submitted to BARDA representative or COR within 24 hours of FDA notification.

- Expedited safety reports of serious and unexpected adverse experiences. A copy of any report of unexpected and serious adverse experience associated with use of an IND drug or any finding from tests in laboratory animals that suggests a significant risk for human subjects, which must be reported in writing to FDA as soon as possible but no later than 15 day after the IND sponsor's receipt of the information, must be submitted to the BARDA representative or COR within 24 hours of FDA notification.

- IDE reports of unanticipated adverse device effect. A copy of any reports of unanticipated adverse device effect submitted to FDA must be submitted to BARDA representative or COR within 24 hours of FDA notification.

- Expedited safety reports. Sent to BARDA representative or the COR concurrently with the report to FDA.

- Other adverse events documented during the course of the trial should be included in the annual IND or IDE report and reported to BARDA annually.

b. Safety reporting for research not performed under an IND or IDE:

Final decisions regarding ongoing safety reporting requirements for research not performed under an IND or IDE must be made jointly by the BARDA PO or the COR and the Contractor.

In case of problems or issues the COR will contact the Contractor within ten (10) working days by email or fax, followed within thirty (30) calendar days by an official letter to the Contractor's Project Manager, with a copy to the institutions' office of sponsored programs, listing issues and appropriate actions to be discussed.

c. Human Material (Assurance of OHRP Compliance).

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by Contractor in full compliance with applicable Federal, State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by Contractor.

Provision by the Contractor to the CO of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self-designated form provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

PART II. CONTRACT CLAUSES

SECTION I. – CONTRACT CLAUSES

I.I. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at: http://www.acquisition.gov/far. HHSAR clauses at http://www.hhs.gov/policies/hhsar/subpart352.html

General Clauses for Firm-Fixed Price Research and Development Contract

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

Reg	Clause	Date	Clause Title
FAR	52.202-1	Nov 2013	Definitions
FAR	52.203-3	Apr 1984	Gratuities
FAR	52.203-5	May 2014	Covenant Against Contingent Fees
FAR	52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government
FAR	52.203-7	May 2014	Anti-Kickback Procedures
FAR	52.203-8	May 2014	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity
FAR	52.203-10	May 2014	Price or Fee Adjustment for Illegal or Improper Activity
FAR	52.203-11	Sept 2007	Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions
FAR	52.203-12	Oct 2010	Limitation on Payments to Influence Certain Federal Transactions
FAR	52.203-13	Oct 2015	Contractor Code of Business Ethics and Conduct
FAR	52.203-14	Oct 2015	Display of Hotline Poster(s)
FAR	52.203-17	Apr 2014	Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights
FAR	52.204-1	Dec 1989	Administrative Matters Provisions and Clauses
FAR	52.204-4	May 2011	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper
FAR	52.204-7	Jul 2016	System for Award Management
FAR	52.204-8	Oct 2018	Annual Representations and Certifications
FAR	52.204-10	Oct 2016	Reporting Executive Compensation and First-Tier Subcontract Awards
FAR	52.204-13	Oct 2016	System for Award Management Maintenance
FAR	52.204-18	Jul 2015	Commercial and Government Entity Code Maintenance
FAR	52.207-1	May 2006	Notice of Standard Competition
FAR	52.209-6	Oct 2015	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment
FAR	52.209-9	Jul 2013	Updates of Publicly Available Information Regarding Responsibility Matters
FAR	52.209-10	Nov 2015	Prohibition on Contracting with Inverted Domestic Corporations
FAR	52.210-1	Apr 2011	Market Research
FAR	52.211-5	Aug 2000	Material Requirements

FAR	52.215-2	Oct 2010	Audit and Records – Negotiation
FAR	52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
FAR	52.215-10	Aug 2011	Price Reduction for Defective Cost or Pricing Data
FAR	52.215-14	Oct 2010	Integrity of Unit Prices (Over the Simplified Acquisition Threshold
FAR	52.215-15	Oct 2010	Pension Adjustments and Asset Reversions
FAR	52.215-18	Jul 2005	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) other than Pensions
FAR	52.215-19	Oct 1997	Notification of Ownership Changes
FAR	52.215-22	Oct 2009	Limitations on Pass-Through Charges—Identification of Subcontract Effort
FAR	52.215-23	Oct 2009	Limitations on Pass-Through Charges
FAR	52.217-9	Mar 2000	Option to Extend the Term of the Contract
FAR	52.219-8	Oct 2014	Utilization of Small Business Concerns
FAR	52.219-9	Oct 2015	Small Business Subcontracting Plan
FAR	52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan
FAR	52.219-28	Jul 2013	Post-Award Small Business Program Representation
FAR	52.222-3	Jun 2003	Convict Labor
FAR	52.222-21	Apr 2015	Prohibition of Segregated Facilities
FAR	52.222-24	Feb 1999	Pre-award On-Site Equal Opportunity Compliance Evaluation
FAR	52.222-25	Apr 1984	Affirmative Action Compliance
FAR	52.222-26	Sept 2016	Equal Opportunity
FAR	52.222-35	Oct 2015	Equal Opportunity for Veterans ($150,000 or more)
FAR	52.222-36	Jul 2014	Equal Opportunity for Workers with Disabilities
FAR	52.222-37	Feb 2016	Employment Reports on Veterans
FAR	52.222-38	Feb 2016	Compliance with Veterans' Employment Reporting Requirements
FAR	52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act
FAR	52.222-50	Mar 2015	Combating Trafficking in Persons
FAR	52.222-54	Oct 2015	Employment Eligibility Verification
FAR	52.222-62	Jan 2017	Paid Sick Leave Under Executive Order 13706
FAR	52.223-6	May 2001	Drug-Free Workplace
FAR	52.223-18	Aug 2011	Encouraging Contractor Policy to Ban Text Messaging While Driving
FAR	52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
FAR	52.225-25	Oct 2015	Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran—Representation and Certifications
FAR	52.226-1	Jun 2000	Utilization of Indian Organizations and Indian-Owned Economic Enterprises.
FAR	52.227-1	Dec 2007	Authorization and Consent, Alternate 1 (APR 1984)
FAR	52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement
FAR	52.227-3	Apr 1984	Patent Indemnity
FAR	52.227-11	May 2014	Patent Rights – Ownership by the Contractor
FAR	52.227-14	May 2014	Rights in Data – General

FAR	52.227-15	Dec 2007	Representation of Limited Rights Data and Restricted Computer Software
FAR	52.227-16	June 1987	Additional Data Requirements
FAR	52.228-7	Mar 1996	Insurance – Liability to Third Persons
FAR	52.230-3	Oct 2015	Disclosure and Consistency of Cost Accounting Practices
FAR	52.230-6	Jun 2010	Administration of Cost Accounting Standards
FAR	52.232-2	Apr 1984	Payments Under Fixed-Price Research and Development Contracts
FAR	52.232-9	Apr 1984	Limitation on Withholding of Payments
FAR	52.232-17	May 2014	Interest
FAR	52.232-20	Apr 1984	Limitation of Cost
FAR	52.232-23	May 2014	Assignment of Claims
FAR	52.232-25	Jan 2017	Prompt Payment
FAR	52.232-33	Jul 2013	Payment by Electronic Funds Transfer–System for Award Management
FAR	52.232.39	Jun 2013	Unenforceability of Unauthorized Obligations
FAR	52.232-40	Dec 2013	Providing Accelerated Payments to Small Business Subcontractors
FAR	52.233-1	May 2014	Disputes
FAR	52.233-2	Sep 2006	Service of Protest
FAR	52.233-3	Aug 1996	Protest After Award
FAR	52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
FAR	52.242-1	Apr 1984	Notice of Intent to Disallow Costs
FAR	52.242-3	May 2014	Penalties for Unallowable Costs
FAR	52.242-4	Jan 1997	Certification of Final Indirect Costs
FAR	52.242-13	Jul 1995	Bankruptcy
FAR	52.242-15	Aug 1989	Stop Work Order
FAR	52.243-1	Aug 1984	Changes – Fixed Price Alternate V
FAR	52.244-2	Oct 2010	Subcontracts, Alternate 1 (Jun 2007)
FAR	52.244-5	Dec 1996	Competition in Subcontracting
FAR	52.244-6	Jan 2019	Subcontracts for Commercial Items
FAR	52.245-1	Apr 2012	Government Property
FAR	52.245-9	Apr 2012	Use and Charges
FAR	52.246-4	Aug 1996	Inspection of Services -- Fixed-Price
FAR	52.246-7	Aug 1996	Inspection of Research and Development -- Fixed-Price
FAR	52.246-9	Aug 1989	Inspection of Research and Development (Short Form)
FAR	52.246-16	Aug 1984	Responsibility for Supplies
FAR	52.246-23	Feb 1997	Limitation of Liability
FAR	52.249-2	Apr 2012	Termination for Convenience of the Government (Fixed-Price)
FAR	52.249-9	Apr 1984	Default (Fixed-Price Research and Development)
FAR	52.253-1	Jan 1991	Computer Generated Forms

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

Reg	Clause	Date	Clause Title
HHSAR	352.203-70	Dec 2015	Anti-Lobbying
HHSAR	352.208-70	Dec 2015	Printing and Duplication
HHSAR	352.211-3	Dec 2015	Paperwork Reduction Act
HHSAR	352.219-70	Dec 2015	Mentor-Protégé Program
HHSAR	352.219-71	Dec 2015	Mentor-Protégé Program Reporting Requirements
HHSAR	352.222-70	Dec 2015	Contractor Cooperation in Equal Employment Opportunity Investigations
HHSAR	352.223-70	Dec 2015	Safety and Health
HHSAR	352.224-70	Dec 2015	Privacy Act
HHSAR	352.224-71	Dec 2016	Confidential Information
HHSAR	352.227-70	Dec 2015	Publications and Publicity
HHSAR	352.233-70	Dec 2015	Choice of Law (Overseas)
HHSAR	352.233-71	Dec 2015	Litigation and Claims
HHSAR	352.237-75	Dec 2015	Key Personnel
HHSAR	352.239-74	Dec 2015	Electronic and Information Technology Accessibility
HHSAR	352.270-5b	Dec 2015	Care of Live Vertebrate Animals.
HHSAR	352.270-6	Dec 2015	Restriction on Use of Human Subjects.
HHSAR	352.270-9	Dec 2015	Non-discrimination for Conscience
HHSAR	352.270-13	Dec 2015	Continued Ban on Funding Abortion and Continued Ban on Funding of Human Embryo Research.

I.II. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

This contract incorporates the following clauses in full text. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

FAR 52.204-21 Basic Safeguarding of Covered Contractor Information Systems (Jun 2016)

(a) *Definitions*. As used in this clause--

"Covered contractor information system" means an information system that is owned or operated by a contractor that processes, stores, or transmits Federal contract information.

"Federal contract information" means information, not intended for public release, that is provided by or generated for the Government under a contract to develop or deliver a product or service to the Government, but not including information provided by the Government to the public (such as on public Web sites) or simple transactional information, such as necessary to process payments.

"Information" means any communication or representation of knowledge such as facts, data, or opinions, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual (Committee on National Security Systems Instruction (CNSSI) 4009).

"Information system" means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information (44 U.S.C. 3502).

"Safeguarding" means measures or controls that are prescribed to protect information systems.

(b) Safeguarding requirements and procedures.

(1) The Contractor shall apply the following basic safeguarding requirements and procedures to protect covered contractor information systems. Requirements and procedures for basic safeguarding of covered contractor information systems shall include, at a minimum, the following security controls:

(i) Limit information system access to authorized users, processes acting on behalf of authorized users, or devices (including other information systems).

(ii) Limit information system access to the types of transactions and functions that authorized users are permitted to execute.
(iii) Verify and control/limit connections to and use of external information systems.
(iv) Control information posted or processed on publicly accessible information systems.
(v) Identify information system users, processes acting on behalf of users, or devices.
(vi) Authenticate (or verify) the identities of those users, processes, or devices, as a prerequisite to allowing access to organizational information systems.
(vii) Sanitize or destroy information system media containing Federal Contract Information before disposal or release for reuse.
(viii) Limit physical access to organizational information systems, equipment, and the respective operating environments to authorized individuals.
(ix) Escort visitors and monitor visitor activity; maintain audit logs of physical access; and control and manage physical access devices.
(x) Monitor, control, and protect organizational communications (i.e., information transmitted or received by organizational information systems) at the external boundaries and key internal boundaries of the information systems.
(xi) Implement subnetworks for publicly accessible system components that are physically or logically separated from internal networks.
(xii) Identify, report, and correct information and information system flaws in a timely manner.
(xiii) Provide protection from malicious code at appropriate locations within organizational information systems.
(xiv) Update malicious code protection mechanisms when new releases are available.
(xv) Perform periodic scans of the information system and real-time scans of files from external sources as files are downloaded, opened, or executed.

(2) *Other requirements*. This clause does not relieve the Contractor of any other specific safeguarding requirements specified by Federal agencies and departments relating to covered contractor information systems generally or other Federal safeguarding requirements for controlled unclassified information (CUI) as established by Executive Order 13556.

(c) *Subcontracts*. The Contractor shall include the substance of this clause, including this paragraph (c), in subcontracts under this contract (including subcontracts for the acquisition of commercial items, other than commercially available off-the-shelf items), in which the subcontractor may have Federal contract information residing in or transiting through its information system.

FAR 52.219-28 Post-Award Small Business Program Representation (July 2013)

a. *Definitions* . As used in this clause--

Long-term contract means a contract of more than five years in duration, including options. However, the term does not include contracts that exceed five years in duration because the period of performance has been extended for a cumulative period not to exceed six months under the clause at 52.217-8, Option to Extend services, or other appropriate authority.

Small business concern means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (c) of this clause. Such a concern is "not dominant in its field of operation" when it does not exercise a controlling or major influence on a national basis in a kind of business activity in which a number of business concerns are primarily engaged. In determining whether dominance exists, consideration shall be given to all appropriate factors, including volume of business, number of employees, financial resources, competitive status or position, ownership or control of materials, processes, patents, license agreements, facilities, sales territory, and nature of business activity.

b. If the Contractor represented that it was a small business concern prior to award of this contract, the Contractor shall re-represent its size status according to paragraph (e) of this clause or, if applicable, paragraph (g) of this clause, upon the occurrence of any of the following:

(1) Within 30 days after execution of a novation agreement or within 30 days after modification of the contract to include this clause, if the novation agreement was executed prior to inclusion of this clause in the contract.

(2) Within 30 days after a merger or acquisition that does not require a novation or within 30 days after modification of the contract to include this clause, if the merger or acquisition occurred prior to inclusion of this clause in the contract.

(3) For long-term contracts--

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and

(ii) Within 60 to 120 days prior to the date specified in the contract for exercising any option thereafter.

c. The Contractor shall represent its size status in accordance with the size standard in effect at the time of this re-representation that corresponds to the North American Industry Classification System (NAICS) code assigned to this contract. The small business size standard corresponding to this NAICS code can be found at http://www.sba.gov/content/table-small-business-size-standards

d. The small business size standard for a Contractor providing a product which it does not manufacture itself, for a contract other than a construction or service contract, is 500 employees.

e. Except as provided in paragraph (g) of this clause, the Contractor shall make the representation required by paragraph (b) of this clause by validating or updating all its representations in the Representations and Certifications Section of the System for Award Management (SAM) and its other data in SAM, as necessary, to ensure that they reflect the Contractor's current status. The Contractor shall notify the contracting office in writing within the timeframes specified in paragraph (b) of this clause that the data have been validated or updated, and provide the date of the validation or update.

f. If the Contractor represented that it was other than a small business concern prior to award of this contract, the Contractor may, but is not required to, take the actions required by paragraphs (e) or (g) of this clause.

g. If the Contractor does not have representations and certifications in SAM, or does not have a representation in SAM for the NAICS code applicable to this contract, the Contractor is required to complete the following representation and submit it to the contracting office, along with the contract number and the date on which the representation was completed:

The Contractor represents that it [X] is, [ ] is not a small business concern under NAICS Code **541715** assigned to contract number 75A50119C00043.

FAR 52.227-7 Patents – Notice of Government License (APR 1984)

The Government is obligated to pay a royalty applicable to the proposed acquisition because of a license agreement between the Government and the patent owner. The patent number is ____ *[Contracting Officer fill in],* and the royalty rate is ____ *[Contracting Officer fill in]*. If the offeror is the owner of, or a licensee under, the patent, indicate below:

☐ **Owner**
☐ **Licensee**

If an offeror does not indicate that it is the owner or a licensee of the patent, its offer will be evaluated by adding thereto an amount equal to the royalty

I.III. ADDITIONAL HHSAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

HHSAR 352.231-70 – Salary Rate Limitation (Dec 2015)

i. Pursuant to the current and applicable prior HHS appropriations acts, payment of the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II in effect on the date Government funding was initially obligated to this Agreement is an unallowable cost under this Agreement and shall be addressed in accordance with Article.

ii. For purposes of the salary rate limitation, the terms "direct salary," "salary", and "institutional base salary", have the same meaning and are collectively referred to as "direct salary", in this clause. An individual's direct salary is the annual compensation that the Recipient pays for an individual's direct effort (costs) under theaward . Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Recipient. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative [F&A] costs).

Note: The salary rate limitation does not restrict the salary that an organization may pay an individual working under a Government award; it merely limits the portion of that salary that may be paid with Federal funds.

iii. The salary rate limitation also applies to individuals under Sub-Recipient Agreements except to the extent that that a Sub-Recipient Agreement is awarded on a fixed-price basis without analysis of labor costs. If this is a multiple-year award, it may be subject to unilateral modification by the CO to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act in effect when the expense is incurred regardless of the rate initially used to establish Agreement funding.

iv. See the salaries and wages pay tables on the U.S. Office of Personnel Management Web site for Federal Executive Schedule salary levels that apply to the current and prior periods.

PART III. LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J. LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

a. Statement of Work, dated 25 July 2019
b. Sample Invoice Request
c. Schedule of Payments
d. Brief Commercialization Plan

PART IV. REPRESENTATIONS AND INSTRUCTIONS

SECTION K. REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

The following documents are incorporated by reference in this contract:

a. Animal Research Assurance Identification Numbers: To be provided prior to study execution.
b. Human Subjects Assurance Identification Numbers: To be provided prior to study execution.

Attachment 1

Biomedical Advanced Research and Development Authority (BARDA)
Broad Agency Announcement BAA-18-100-SOL-00018

Title: Advanced, Bio-Integrated, and Cloud-Enabled Sensors for Early Diagnosis of Respiratory Infections in the Home Setting

Area of Interest #1 (ENACT)

Contractual Statement of Work

PREAMBLE

Independently, and not as an agent of the government, the contractor shall furnish all necessary services; qualified professional, technical, and administrative personnel; and material, equipment, and facilities not otherwise provided by the government under the terms of this contract, as needed to perform the tasks set forth below.

The government reserves the right to modify the budget, progress, schedule, or milestones to add or delete processes, schedules, or deliverables if the need arises. Because of the nature of this research and development (R&D) contract and the complexities inherent in this and prior programs, at designated milestones the government will evaluate whether work should be redirected or removed, or whether schedule or budget adjustments should be made. The government reserves the right to change the product, process, schedule, or events to add or delete part or all of these elements as the need arises.

Overall Objectives and Scope

The overall objective of this contract is to modify, augment, and validate our advanced, bio-integrated wireless sensor (ADAM) to monitor, predict, and track respiratory infections in high-risk populations such as individuals with chronic obstructive pulmonary disease.

The scope of work for this contract includes key engineering modifications and improvements to the ADAM sensor for deployment in this context. Specifically, this includes modifications to the underlying hardware and firmware software to accommodate 7-days of memory storage and battery life on a single charge. In addition, a new mobile application will be developed to allow for easy patient navigation and facilitate data collection. Finally, a single-arm prospective observational clinical study in the intended population (patients with a diagnosis of chronic obstructive pulmonary disease and a prior history of pneumonia) will be conducted. This study will evaluate the predictive value of the ADAM sensor outputs with clinically significant respiratory infections.

The R&D effort for [Advanced, Bio-Integrated, and Cloud-Enabled Sensors for Early Diagnosis of Respiratory Infections in the Home Setting] will progress in phases that cover the base performance segment to be labeled Contract Line Item Number (CLIN) 0001. The scope of work is broken into the following phases:

Phase I

AIM 1: Hardware Engineering Deliverables: we propose to extend the battery and memory storage of the existing ADAM (24 hours battery life and memory capacity) by 700% to 7 days battery life / memory capacity on a single charge to reduce user burden.

AIM 2: Software Engineering Deliverables: we propose to develop a custom mobile application specific to this engagement. This effort will occur concomitantly with AIM 1.

Phase II

AIM 3: Clinical Deliverables: at Northwestern University, we will conduct a single-arm, prospective clinical study to evaluate the predictive power of ADAM sensors for respiratory infection in a high-risk population of patients with chronic obstructive pulmonary disease and a prior history of pneumonia. This will occur on a weekly basis for 52 weeks.

AIM 4: Data Analytics Deliverables: after completion of enrollment, we will deploy a range of biostatistical and machine learning techniques to correlate ADAM sensor outputs with clinical events recorded in the medical record and patient-reported outcomes via the custom mobile application. This will yield a set of novel algorithms specific to the ADAM sensor system that will be further validated in a follow-on, larger clinical study.

1. **PHASE 1: Engineering Optimization of the ADAM System for Respiratory Infections**

AIM 1: Hardware Augmentation of the ADAM Sensor System

We propose changes to our underlying circuitry and design to incorporate a 70 mAh battery that will have minimal impact on the overall dimensions and weight of the ADAM system. This includes identification and board testing of a larger capacity lithium ion battery, changes to the underlying circuit board firmware software changes that will maintain low-power operation. A larger memory capacity chip will also be implemented. The addition of a new battery will then require electrical safety validation for operation and charging. Safety testing will be conducted to ensure correct operation of the dual battery protection levels provided by two different battery management integrated circuits that follow JEITA standards. In addition, we will ensure minimal thermal load generation with operation and battery safety before pursuing clinical studies.

Objective: augment and modify the ADAM sensor for 7 days of continuous operation on a single charge.

Deliverable: 100 sets of the ADAM sensor with extended 7-day operation capabilities

Success criteria for completion of AIM 1:
-Successful manufacturing of 100 sets of ADAM sensors with extended 7-day operation capabilities
-Bench report testing of power performance of ADAM sensors with >95% of ADAM sensors reaching 7 days (168 hours) of run time
-Bench report testing of memory capacity of ADAM sensors with >95% of ADAM sensors reaching 7 days (168 hours) of memory time
-Bench report testing of thermal safety of ADAM sensors with <0% generating 5 °C after 24 hours of continuous operation

AIM 2: Custom Mobile Application Development

We propose to develop an highly simplified mobile application that facilitates data collection and upload. This application will allow for straight forward patient use including those of limited technological literacy. This will occur concomitantly with AIM 1. First, we will design a fully "clickable" user interface. Beta testing by Sonica engineers will be done to ensure easy to understand functionality. After a locked user interface, we will complete front-end application development for a new custom mobile application. This will include testing and validation with our backend system. Cloud-integration will also be tested where data from the mobile application directly is pushed to the cloud in a HIPAA-compliant manner.

Objective: develop a custom mobile application with cloud integration for the ADAM sensor to be used in the context of this program.

Deliverable: the deliverable includes design deliverables around a new mobile application, front-end mobile application development, integration with our existing backend code, and

Success criteria for completion of AIM 2:
-Completed user interface design with full click through functionality
-Fully functional mobile application with cloud integration capabilities
-Sandbox environment enabling full operation of the ADAM sensors with the new mobile application

2. **PHASE 2: Clinical Deployment of the ADAM System for Respiratory Infections**

AIM 3: Clinical Validation Testing

At Northwestern University, we will conduct a single-arm, prospective clinical study to evaluate the predictive power of ADAM sensors for respiratory infection in a high-risk population. In a cohort of patients with a diagnosis of COPD on inhaled corticosteroids and prior inpatient/ICU admission for pneumonia, we

will deploy ADAM sensors for up to 52 weeks. A clinical research assistant will check-in with study subjects weekly with financial compensation given on a biweekly basis to boost engagement. We select COPD patients on inhaled corticosteroids with a prior respiratory infection due to their high risk of recurrent infections (88 per 1,000 person-years). Clinical diagnoses of respiratory infections will be determined via tracking of the patient's electronic medical record at Northwestern Memorial Health. Our power analysis suggest a target recruitment of 122 subjects to yield 10 instances of community acquired pneumonia providing sensitivity and specificity scores for the ADAM sensor system. Finally, we conducted an initial i2b2 software search of ICD-10 codes for COPD, pneumonia (influenza or bacterial) that identified 1,500 eligible patients in the Northwestern system providing a rich substrate for recruitment.

Objective: the objective of this Aim is to establish critical validation data of the multi-modal data outputs of the ADAM sensor can monitor, predict, and track respiratory infections in a high-risk cohort. The secondary objective of this Aim is to demonstrate subject adherence to the protocol, and sensor usability in this population.

Deliverable: demonstration of successful sensor deployment, usability, and adherence by subject participants. On scheduled 6, 9, and 12 month interim data evaluations, we expect to provide preliminary evidence of the sensitivity, specificity, positive predictive value, and negative predictive value of ADAM sensor outputs for clinically diagnosed respiratory infections.

Success criteria for completion of AIM 3:
->70% weekly compliance with the ADAM sensor
-<20% data loss secondary to device failure

AIM 4: Data Analytics Development

We will deploy a range of biostatistical and machine learning techniques to correlate ADAM sensor outputs with clinical events recorded in the medical record and patient-reported outcomes via the custom mobile application. This will allow us to develop a predictive algorithm from the continuous data streams days or even weeks ahead of a clinically significant respiratory infection event that will be validated in a follow-on, larger clinical study. Our group has a wide range of techniques including continuous wavelet transforms, Fourier transforms, convolutional and recurrent neural networks, and multi-variate regression techniques. The finalized strategy will depend on the data collected.

Objective: development of novel algorithms using ADAM data outputs to assess clinically relevant respiratory infections.

Deliverable: Our deliverables here include predictive algorithms with adjustable confidence thresholds that can be deployed on a cloud-based user interface. The data generated will also warrant a pre-510(k) submission meeting with the FDA.

Success criteria for completion of AIM 4:
->70% of sensitivity for respiratory infection in a high-risk COPD cohort justifying further development and validation of the ADAM system in a larger, follow-on clinical study

3.1 PROGRAM MANAGEMENT

The contractor shall provide the following as outlined below and in the contract deliverables:

3.1.1 The overall management, integration, and coordination of all contract activities, including a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and direction of all contract activities;

3.1.2 A principal investigator (PI) or project manager (PM) responsible for project management, communication, tracking, monitoring, and reporting on status, progress, and modification to the project requirements and timelines, including projects undertaken by subcontractors. The contract deliverables list identifies all contract

deliverables and reporting requirements for this contract;

3.1.3 A project manager with responsibility for monitoring and tracking day-to- day progress and timelines; coordinating communication and project activities; costs incurred; and program management. The contract deliverables list identifies all contract deliverables and reporting requirements for this contract;

3.1.4 A BARDA liaison with responsibility for effective communication with the Contracting Officer (CO) and Contracting Officer's Representative (COR). The liaison may be the PM;

3.1.5 Administrative and legal staff capability with responsibility for developing compliant subcontracts, consulting, and other legal agreements; ensuring timely acquisition of all proprietary rights, including intellectual property (IP) rights; and reporting all inventions made in the performance of the contract;

3.1.6 Administrative staff capability with responsibility for financial management and reporting on all activities conducted by the contractor and any subcontractors;

3.1.7 Contract Review Meetings;

3.1.7.1 The contractor shall participate in regular meetings to coordinate and oversee the contract effort conjointly with the CO and COR. Such meetings may include, but are not limited to, meeting of the contractors and subcontractors to discuss clinical manufacturing progress, product development, product assay development, scale-up manufacturing development, clinical sample assays development, preclinical/clinical study designs and regulatory issues; meetings with individual contractors and other government officials to discuss the technical, regulatory, and ethical aspects of the program; and meetings with technical consultants to discuss technical data provided by the contractor; and

3.1.7.2 The contractor shall participate in teleconferences every month with the CO and COR to discuss the performance of the contract, unless otherwise directed. Teleconferences or additional face-to-face meetings may be more frequent at the request of the CO.

3.1.8 Gantt Chart

3.1.8.1 Within 30 calendar days of the effective date of the contract, the contractor shall submit a first draft of an updated Gantt Chart to the CO and COR for review and comment. The Gantt Chart shall be incorporated into the contract and will be used to monitor performance of the contract. The contractor shall include the key milestones and Go/No-Go Decision Gates.

3.1.8.2 Project Management Plan: In the management of this contract, the contractor shall utilize Project Progress Management tools/techniques to track and monitor the cost and schedule of the project. The contractor and the government agree that at a minimum, the contractor shall utilize the cost and schedule tools/techniques in the contract deliverable for project management purposes. The contractor shall submit the project progress management report to the CO and COR on a monthly basis.

3.1.9 Risk Management Plan: The contractor shall develop a risk management plan within 90 days of contract award highlighting potential problems and/or issues that may arise during the life of the contract; their impact on cost, schedule, and performance; and appropriate remediation plans. This plan should reference relevant WBS elements where appropriate. Updates to this plan shall be included, at a minimum, on a quarterly basis (every three

months) in the monthly Project Status Report.

3.1.10 Monthly and Annual Reports: If requested, the contractor shall deliver Project Status Reports on a monthly basis. The reports shall address the items below cross referenced to the SOW, WBS, IMS, and EVM or other Project Management Plan tool(s):

i. Executive summary highlighting the progress, issues, and relevant manufacturing, non-clinical, clinical, and regulatory activities;
ii. Progress in meeting contract milestones, detailing the planned progress and actual progress during the reporting period, explaining any differences between the two and corrective steps;
iii. Updated Risk Management Plan (every three months);
iv. Three-month rolling forecast of planned activities;
v. Progress of regulatory submissions

3.1.11 Data Management: The contractor shall develop and implement data management and quality control systems/procedures, including transmission, storage, confidentiality, and retrieval of all contract data;

3.1.12 Provide for the statistical design and analysis of data resulting from the research; and

3.1.13 Provide raw data or specific analyses of data generated with contract funding to the CO and COR, upon request.

3.2 REGULATORY

3.2.1 Engage the Food and Drug Administration (FDA) on a path to support the use of the product for the specific indication;

3.2.2 Prepare materials for and requesting, scheduling, and participating in all meetings with the FDA, including meetings to review all data packages; and

3.2.3 Provide BARDA with (i) the initial draft minutes and final draft minutes of any formal meeting with the FDA, and (ii) final draft minutes of any informal meeting with the FDA.

4.1 FACILITIES, EQUIPMENT, & OTHER RESOURCES

The contractor shall provide equipment; facilities and other resources required for implementation of the SOW to comply with all Federal and HHS regulations in:

4.1.1 The humane care and use of vertebrate animals;

4.1.2. The acquisition, handling, storage, and shipment of potentially dangerous biological and chemical agents, including select agents under biosafety levels required for working with the biological agents under study.

Attachment 2

SAMPLE INVOICE REQUEST

(a) Designated Billing Office Name and Address:

DHHS/OS/ASPR/BARDA
ATTN: Contracting Officer
O'Neill House Office Building
Washington, DC 20515

(b) Contractor's Name:

_____

Contractor's Address

_____

_____

_____

Contractor's EIN: _____

Contractor's CAGE: _____

Contractor's DUNS: _____

Point of Contact Name, Title, Email, Phone:

_____

_____

_____

_____

(c) Invoice No.: _____

(d) Date Invoice Submitted: _____

(e) Contract No.: _____

(f) Current Contract Period of Performance:

_____

(g) Total Price of Contract: _____

(h) Total Fixed-Fee (if applicable): _____

(i) Invoicing Type: Three-Way Match

(j) Office of Acquisitions:

DHHS/OS/ASPR/BARDA
ATTN: Contracting Officer
O'Neill House Office Building
Washington, DC 20515

(k) Central Point of Distribution: N/A

(l) This invoicing request represents reimbursable costs for the period from:

CLIN No.	Unit	(m) Current Amount	(n) Cumulative Amount	(o) Total Contract Amount
_____	_____	_____	_____	_____

Brief description of the work/deliverable(s) being invoiced:

I certify that all payments are for appropriate purposes and in accordance with the contract.

_____ _____
(Name of Official) (Title)

Note: Please attach supporting documents and details as specified in the contract to support the work/deliverable(s) being invoiced

Attachment 3

Schedule of Payments

Pursuant to FAR 52.232-2, payments will be made upon submission of an acceptable invoice for partial delivery of work, as outlined below in the table. The remaining balance will be paid only upon receipt and acceptance of the (1) Final Data Submission Package & (2) Final Report as described in Section F.2 of the subject contract:

Partial Payment	SOW Deliverable	Description	Partial Payment Amount
1	Project Plan, Gantt Chart, and kick off meeting	All to be done within 30 days after award	$50,000
2	Phase I Aim I and Aim II Deliverables	-Successful manufacturing of 100 sets of ADAM sensors with extended 7-day operation capabilities -Bench report testing of power performance of ADAM sensors with >95% of ADAM sensors reaching 7 days (168 hours) of run time -Bench report testing of memory capacity of ADAM sensors with >95% of ADAM sensors reaching 7 days (168 hours) of memory time -Bench report testing of thermal safety of ADAM sensors with <0% generating 5 °C after 24 hours of continuous operation -Completed user interface design with full click through functionality -Fully functional mobile application with cloud integration capabilities -Sandbox environment enabling full operation of the ADAM sensors with the new mobile application	$181,926
3	Phase II Aim I Deliverables	->70% weekly compliance with the ADAM sensor at 6 month interim data check -<20% data loss secondary to device failure at 6 month interim data check	$181,926
4	Phase II Aim II Deliverables	->70% of sensitivity for respiratory infection in a high-risk COPD cohort justifying further development and validation of the ADAM system in a larger, follow-on clinical study -Pre-510(k) submission meeting with the FDA for the ADAM sensor for indication of respiratory health tracking	$242,568

Attachment 4 – Commercialization Plan

Commercialization Plan

Sonica LLC is developing breakthrough diagnostic sensors and assistive technologies in the broad space of post-acute, sub-acute, and home monitoring with a focus on chronic diseases. Driven by an increasingly older population, there is an increased need for rehabilitative services and assistive technologies that function in a naturalistic environment.[1] For instance, there are more than 800,000 new cases of stroke a year, 5 million Americans suffering from Alzheimer's Dementia, 650,000 Americans suffering from Parkinson's Disease, and 11 million Americans suffering from chronic obstructive pulmonary disease (COPD). All of this individuals would directly benefit from technologies that can monitor their health status at home and predict of impending complications prior to the development of more serious or even fatal sequalae.

Overall, the rehabilitative technologies market exceeds $10.5 billion USDs.[2] Despite the far greater direct and indirect medical costs of chronic diseases, technologies for home monitoring have remained limited. Convenient, low burden technologies (e.g. bathroom scales) provide limited data. High fidelity, comprehensive monitoring systems (e.g. Holter monitors) are too bulky, require a multitude of wires, and expensive. Many of these measurements are only intermittent and not continuous. Thus, there is a market need for a sensor system able to collect high quality data in a continuous way that facilitates home use.

Deployment in specific use cases provide attractive commercialization opportunities. Specifically for this program, respiratory infections remain a critical problem in a wide range of patients with chronic diseases. Across all chronic diseases, COPD is one condition where respiratory infection represents a tremendous driver of morbidity and mortality. Thus, a sensor that predicts for respiratory infection in this high risk population will allow for potential early intervention such as antibiotics prior to more serious clinical deterioration including sepsis or an expensive ER visit. Given the greater shift of payment models towards quality outcomes and capitation over fee for service, technologies such as those being commercialized by Sonica LLC will gain accelerated market adoption.

Regulatory: the commercialization of the ADAM sensor requires achievement of key regulatory endpoints. The hardware itself is a non-significant risk diagnostic technology and classified as a Class II medical device. This means that it is eligible for clearance via the 510(k) clearance pathway. Several relevant predicts exist for ADAM depending on the indication of use – namely actigraphy watch systems (e.g. GT3X Activity Monitor or WATCH-PAT200-2 System) for

[1] NIH initiative tests in-home technology to help older adults age in place. National Institutes on Aging - 2017. goo.gl/K4hNsP
[2] Grand View Research. Rehabilitation Devices/Equipment Market Analysis By Product Type, (Daily Living Aids, Mobility Equipment, Exercise Equipment, Body Support Devices), By Application, By End-use, By Region, And Segment Forecasts, 2018 – 2025. 2017.

tracking physical activity and motion. Additional predicates exist for heart rate and respiratory rate monitoring via wireless sensors as well.

The algorithms—enabled by this program—represents another regulatory challenge. This will require a discussion with the FDA regarding additional clinical data required for the proposed indication of predicting respiratory infection in an adult, high-risk population. Currently, the *de novo* pathway is our expected approval pathway for the ADAM sensor to detect and warn of respiratory infection in a high-risk population.

Reimbursement: After approval, reimbursement codes are necessary to support technology uptick and use. Most recently, the Centers of Medicare and Medicaid Reimbursement recently unbundled CPT 99091 for remote patient monitoring that is asynchronous in nature. ADAM will qualify under this code allowing for providers to charge insurers for the use of the technology and interpretation of the data. This is an important CPT code that negates the need for ADAM to achieve its own CPT code, which takes several years to successfully secure.

Manufacturing: we have long-established relationships with a wide range of vendors and manufacturers to produce ADAM devices. Thus, our technology already has proven manufacturability with the ability to upscale to 10,000s of units as needed.

Domestic - *QTY of 100's-10,000's*

MULTEK — Minnesota

Techprint — Massachusetts

Altaflex, A Division of CTI Electronics — California

UNIFLEX CIRCUITS — California

HANA — Ohio

eAgile RFID Made Easy® — Michigan

ALINE — California

POTOMAC — Maryland

PLASMA RUGGEDIZED SOLUTIONS — California

International-*QTY 10,000's-10M+*

PFC FLEXIBLE CIRCUITS LIMITED

ICH International

pch